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DICKSTEIN SHAPIRO LLP
1825 EYE STREET NW
Washington, DC 20006-5403

EXAMINER	
HUPCZEY, JR, RONALD JAMES	

ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,229	EISELE, FLORIAN	
	Examiner	Art Unit	
	RONALD HUPCZEY, JR	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and remarks, received on April 16th, 2010 have been fully considered by the examiner. Claims 1-6 and 8-20 are currently pending with claim 1 amended and claim 7 cancelled. Applicant's amendment to claim 1 has obviated the rejection of the claims under 35 U.S.C. 112 1st and 2nd paragraphs as well as obviated the object to the claim. The following is a complete response to the April 16th, 2010 communication.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 6, 8-10, 12-13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Rioux et al (US Pat. Pub. 2005/0171525 A1).

Regarding claim 1, Rioux discloses an apparatus for the interstitial coagulation of tissue (as best seen in figures 11 and 12) comprising a first three-dimensional treatment electrode (see figures 11 and 12) that can be expanded to various states of expansion during use (from inflation via lumen **1112**) and is capable of conducting an HF coagulation current into said tissue (via conductive element **130** as shown in figure 1 supplying energy to outer balloon **1127**), the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (via supply of fluid from lumens **1112**/**1114**). Rioux further discloses that the treatment electrode

comprises one of an elastically stretchable and an unfoldable surface element (outer balloon **1127**) that defines a separate interior space (area inside of balloon **1127** including interiors **1125/1129**), the interior space (interior space **1125**) being enclosed by an auxiliary body (inner balloon **1123**) that hydraulically separates the enclosed interior space from the surface element (see figure 12 depicting the inner balloon having no holes/pores therethrough and paragraphs [0040]-[0043]) to which wherein an internal pressure can be applied to the enclosed interior space to expand said surface element and thereby said treatment electrode (via lumen **1112**). Lastly, Rioux discloses a liquid-supply through which an electrically conductive liquid can be delivered to the surface element (lumen **1114** as depicted in figure 11) wherein the surface element is configured to receive the electrically conductive liquid from the liquid-supply (via lumen **1114** opening to interior space **1129** which is in fluid communication with the outer balloon **1127**).

Regarding claim 2, Rioux discloses a control device (see the control system depicted in figure 14) that is provided for controlling the degree of expansion of the treatment electrode dependent on said coagulation current (see paragraphs [0046]-[0048], [0041]-[0043] and [0038—[0039]).

Regarding claim 3, Rioux discloses a control device is capable to enable an adjustment of a current density of said coagulation current between said treatment electrode and said tissue (RF generator **1440** with impedance system **1450** as in paragraph [0046]).

Regarding claim 6, Rioux discloses a current supply device capable of delivering the HF coagulation current to said treatment electrode in such a way that said HF treatment current conducted to the liquid that is passing through the treatment electrode (conductive element

130/1430 of figures 1/14 connected to RF generator **1440** in view of the disclosure in paragraphs [0041]-[0042]).

Regarding claim 8, Rioux discloses that the surface element is in the form of one of a ring and a sphere (see figure 11).

Regarding claim 9, Rioux discloses that the treatment electrode is constructed in the form of a balloon catheter (see figure 11 showing inner and outer balloons **1123/1127**).

Regarding claim 10, Rioux discloses that the surface element is capable of being filled with said electrically conductive liquid (outer balloon **1127** with interior space **1129** being filled via lumen **1114** to be filled with fluid as disclosed in paragraphs [0040]-[0042]).

Regarding claim 12, Rioux discloses that the treatment electrode is made of a thermally stable material; the form of one of a film, a felt and a woven fabric (see paragraph [0026] discussing the construction of the balloons of the device).

Regarding claim 13, Rioux discloses that surface element (outer balloon **1127/1227**) is constructed in several layers such that in an inner layer (inner portion of the outer balloon **1127/1227** which is formed from a conductive material as in paragraph [0028] and contains the bumps as seen in figure 12), electrically conductive liquid can be directed towards an outer surface of the element (via opening in the bumps as shown in figure 12) and in an outer layer (outer conductive layer provided on the inner layer as in paragraph [0028], as seen in figure 12 as the smooth outer surface) electrically conductive liquid can be directed perpendicular to the outer surface of the element (via flowing out of the pores of the balloon shown in figure 12).

Regarding claim 15, Rioux discloses that the electrode is capable of being supplied with a cutting current (supply of energy via RF generator **1440**).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al (US Pat. Pub. 2005/0171525 A1).

Regarding claim 4, Rioux fails to specifically recite that the control system of figure 14 provides the functionality of permitting the current density to be adjusted independently of the degree of expansion. However, in light of the disclosure of paragraphs [0045]-[0047] discussing the function of the various portions of the control system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a manual control over each of the parameters of the treatment system such that the user could individually adjust the system as seen fit during treatment. The provision of manual control of electrosurgical systems is well known in the art and commonly provided for in order to allow the operator control over the

device in instances which the device does not behave correctly given its programming or needs to be stopped in an emergency if an error occurs (current density brought manually to zero).

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al (US Pat. Pub. 2005/0171525 A1) as applied to claim 1 above, and further in view of Lennox et al (US Pat. No. 5,545,195).

Regarding claim 5, while Rioux is concerned with the amount of fluid flow through the treatment device via a fluid regulator **1460**, Rioux fails to disclose a measurement devices are provided for detecting the state of expansion of said three-dimensional treatment electrode. Lennox discloses an analogous device containing a three-dimensional body which can be expanded to a plurality of expanded states containing at least one electrode. Lennox further discloses a measurement device to detect the state of expansion of the three-dimensional body (syringe **224** and its displacement, see col. 4; 2-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide such a fluid supply and monitoring device as that of Lennox in conjunction with the device of Rioux in order to ascertain the amount of fluid and level of expansion of the three-dimensional body of Rioux. As demonstrated by Lennox, the provision of monitoring the expansion of the three-dimensional body of a device such as that of Rioux is well known in the art and such monitoring ensures the three-dimensional body is expanded to a safe level, not exposed to excessive amounts of pressure and does not apply excess pressure to the body lumen or space in which it is inserted.

8. Claim 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al (US Pat. Pub. 2005/0171525 A1) as applied to claim 6 above, and further in view of Koblish et al (US Pat. No. 6,937,885 B2).

Regarding claim 14, while Rioux discloses in other exemplary embodiments, namely that of figure 10, the use of a circulation of fluid within a balloon, Rioux fails to specifically recite the providing of a suction device as claimed. Koblish discloses a similar device as that of Rioux comprising a first three-dimensional treatment electrode (inflatable therapeutic element **14** with non-porous region **30,** porous region **26** and in relation with electrode **32**) that can be expanded to various states of expansion during use (various states occurring from expansion from collapsed state to expanded state) and is capable to conduct an HF coagulation current into said tissue, the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (inflatable therapeutic element **14** filled with various levels of pressure to maintain tissue contact, see col. 10; 9-30). Koblish further discloses for a suction device to be provided that sucks away liquid (fluid delivery device **72** in conjunction with ventilation lumen **58** removing fluid from the therapeutic element (see col. 9; 30 – col. 10; 9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the suction device of Koblish in combination with the device of Rioux to provide for a means of removing fluid contained within the treatment body **20** when the device is ready to be collapsed and removed from the body.

9. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al (US Pat. Pub. 2005/0171525 A1) in view of Swanson et al (US Pat. No. 5,797,903).

Regarding claim 11, Rioux fails to disclose that the electrically conductive liquid comprises one of polyvinyl pyrrolidone (PVP), a surfactant and a similar means of changing the viscosity of said electrically conductive liquid. Swanson discloses a similar three dimensional

treatment electrode as that of Rioux and further discloses the provision of a viscosity-modifying agent in the electrically conductive fluid (see col. 11; 53-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a viscosity-modifying substance as in Swanson to the electrically conductive fluid of Rioux in order to tailor the flow characteristics of the fluid if Rioux. Rioux is already concerned about outflow rate through the pores depicted in figure 12 (see paragraphs [0041]-[0042]) and in providing another level of adjustment to the fluid rate, the system can provide a more precise and controlled delivery of fluid to the target treatment area thereby ensuring that the over-cooling of the target area does not occur nor does the extension of the treatment margin extend past a desired extent.

Regarding claim 16, Rioux fails to recite that the thermally stable material is comprised of tetrafluoroethylene. Swanson discloses a similar three-dimensional treatment electrode which functions in a similar manner as that of Rioux. Swanson further discloses that the thermally stable material can be tetrafluoroethylene (see col. 7; 66 - col. 8; 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the material of Swanson as the base material of the balloons of Rioux. As exhibited by Swanson, it is well know that such material can function as an expandable balloon and one of ordinary skill in the art would readily recognize the interchangeability of the material of Rioux to the material of Swanson.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al (US Pat. Pub. 2005/0171525 A1) in view of Kokish (US Pat. No. 6,544,223 B1).

Regarding claim 17, while Rioux discloses two layers as in claim 13 above, Rioux fails to a partition layer with a greater resistance to liquid flow than said inner layer is disposed between said inner layer and said outer layer. Kokish discloses a similar expandable member as that of Rioux which delivers fluid through the wall of the expandable member via a plurality of micropores (see figures 3A-3C). Kokish discloses for a first porous layer (layer **32** containing pores **34**) to have on its exterior, a second microporous layer (layer **38** with micropores **40**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an outer layer such as that of Kokish on the existing two layer of Rioux to provide for a combined device which can effectively delivery a fluid through the pores in the wall of the expandable member. Both Rioux and Kokish are concerned with the manipulation and control of fluid flow through the pores (see col. 4; 65 - col. 5; 26 of Kokish and paragraphs [0041]-[0043] of Rioux). In providing such an outer layer, the inner layer of Rioux remains the inner layer and the outer layer becomes the partition layer. The added microporous layer as taught by Kokish becomes the new outer layer. Rioux clearly defines with respect to its layers that the irregular (bumps) surface allows for better fluid flow between the balloons (see paragraphs [0041] and that the fluid flow out of the outer balloon is a function of the opening size (see end of paragraph [0041]). As such, it is clear that the partition layer of the combined device would then have a greater resistance to fluid flow than the inner layer.

11. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al (US Pat. Pub. 2005/0171525 A1) in view of Sahota (US Pat. No. 4,983,167)

Regarding claims 18-20, Rioux discloses the device as shown in the rejection of above claim 1 but fails to disclose the provision of a second treatment electrode. Sahota discloses an

expandable device (as best depicted in figure 5) containing a plurality of expandable bodies (lobes **38**) which are provided with individual inflation ports (ports **42**) which allow for each of the plurality of balloons to be expanded to various states of expansion and to be placed under pressure independently and at different degrees from one another (see col. 6; 38-51). Additionally, as shown in figure 5 of Sahota, the plurality of expandable bodies are coaxial to one another about a center axis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a second treatment electrode in addition to the first treatment electrode of Rioux in light of the teaching of a plurality of expandable bodies independently controllable as in Sahota. Such a provision of a second treatment electrode provides the device with the ability to treat a larger target area of tissue in a single treatment thereby reducing the number of times the device must be repositioned and subsequently, the total treatment time the patient must experience.

Response to Arguments

12. Applicant's arguments with respect to claims 1-6 and 8-20 have been considered but are moot in view of the new ground(s) of rejection. Specifically, Applicant's amendment to claim 1 has necessitated the new grounds of rejection proffered above. In clarifying the relationship between the various structures of the device, the Examiner needed to apply new art to address each of the limitations of claim 1. Similarly, the rejections of claims 2-6 and 8-20 are under new grounds in light of the Rioux reference.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH